UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,597	05/22/2000	John J. Voorhees	1718-009A	1700

7590 12/05/2003

BRADLEY N. RUBEN
463 FIRST ST., SUITE 5A
HOBOKEN, NJ 07030-1859

EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	21

DATE MAILED: 12/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/576,597	VOORHEES ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24,31-39,41-45 and 48-50* is/are pending in the application.

4a) Of the above claim(s) *33-36,41-43 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24,31,32,37-39,44,45,48 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 07/03/2003. As requested, claims 25-30, 40 and 46-47 are canceled and the independent claims 22 and 45, and the dependent thereof are amended.

2. The claims 22-24, 31-39, 41-45 and 48-50 are pending.

3. The previously elected claims 22-24, 31-32, 37-39, 44-45,48 and 50 (see paper17) are presented for the examination.

4. The non-elected claims 33-36, 41-43 and 49 are maintained as withdrawn from the consideration.

Response to Arguments

4. Applicant's arguments with respect to claims 22-50(before amended) have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendment due to the scope changes necessitated the new ground(s) of rejection presented in this Office action.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 22-24, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pikul et al (US 5,830,915) in view of Kumakai(JP08-104628) or Langholz(1995, abstract only)

The instant amended claims are drawn to a method of reducing scarring in acne-affected skin using a topical application of an MMP inhibitor such as genistein, quercetin or a mixture thereof.

Pikul et al (US 5,830,915) teaches an inhibitor of matrix metalloproteases(MMP inhibitors) that can effectively treat and/or prevent scarring(contraction) and acne inflammation, see col. 2, lines 48-50 and claims 27-29. US'915 teaches not only specific MMP inhibitors having general formula I in the patent but also any MMP inhibitors that would , in fact, inhibits the MMPs because MMPs are responsible for the scarring and acne inflammation, see column 2, lines 10-36 and column 3, lines 32-37.

Applicant's claims differ because they require quercetin or genistein as the MMP inhibitors. The claim 23 requires genistein. The claim 24 requires quercetin.

However, it would have been obvious to one of ordinary skill in the art to substitute the compounds(US'915) with quercetin or genistein at the time of the invention was made when US'915 is modified with Langholz(1995) or Kumakai(JP08-104628) because Langholz teaches genistein as a potent MMP inhibitor(see abstract) and JP'628 teaches that quercetin has a potent MMP inhibiting activity, see abstract.

Thus, one would have been motivated to make such modification, with reasonable expectation of success, because the potent MMP inhibitory activity of quercetin or genistein is well proven by the cited reference in addition to the techniques and skills for the said substitution are taught as well. It is always desired to extend the therapeutic modalities. Especially there is always a need for the potent drugs to decrease the side effect(due to small dose required to bring the same therapeutic

effect) and to enhance user's compliance(due to more selection option, less frequent dosage regimen, etc).

One would have been motivated to do so because controlling MMP(e.g. collagenases) activities play the important role on tissue remodeling including preventing and/or treating scar formation where quercetin or genistein is effective MMP inhibitor where its effectiveness and the safety are well proven.

It is conventional knowledge* at the time of the invention was made that the limitation recited in claim 1 (i.e. scarring in acne-affected skin) is embraced by the teaching of US'915 because the scarring ("contraction" of tissue) includes the scarring or contraction of tissue after acne inflammation is modulated by MMPs(e.g. collagenase) as evidenced by numerous documents available in the field, see PTO-892*. Thus, one would have readily envisaged successful reduction of scarring in the acne affected as well as other types of scars because all the scar formations, regardless of the different causative factors such as infection(acne), burn, surgery or accident, share one common characteristic such as erratic accumulation of fibrous tissue rich in collagen and thus, are effectively treated or reduced by modulating the balance of collagen/collagenase pathway as evidenced by US 4524062, see column 1, lines 10-50. Furthermore, the successful reduction of scarring by topical application of genistein or quercetin via MMP inhibition would be readily apparent to one of ordinary skill in the art.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or

similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

7. Claims 31-32, 37-39, 44, 48, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pikul et al (US915) in view of Kumakai(JP628) or Langholz(1995, abstract only) as applied to claims 22-24, 45 above, and further in view of Segot et al(US 6015568).

The teaching of Pikul et al in view of Kumakai or Langholz is mentioned immediately above in 103 rejection(supra).

Applicant's claims differ because they require additional active agent such as retinoid(e.g. retinol) into the said acne-induced scarring reduction therapy(above). The retinoid is combined to treat/prevent not only scarring but also acne itself.

Segot(US'568) teaches that retinol or vitamin A(retinoic acid) based cosmetic or pharmaceutical composition is particularly effective to treat/prevent acne and scarring problems, see .

Thus, it would have been obvious to add retinoid(e.g. retinol) into the genistein or quecetin based therapy at the time of the invention was made because above references in combination make clear that genistein or quercetin and retinoid(e.g.retinol) have been individually used for the treatment of scarring and acne. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is

merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

One would have been motivated to do so because each component is known to be effective and safe where it is readily apparent that the combination would enhance the therapeutic effectiveness.

Conclusion

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675.

The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Primary Patent Examiner
Art unit 1614